

## **REMARKS**

### **I. Preliminary remarks**

Claims 1 and 6 have been amended to recite "an aqueous solution." Support for an external preparation comprising an aqueous solution can be found throughout the application as filed. See, for example, page 7, line 24 to page 8, line 10 and Examples 1-3 in Table 1 on page 7 (wherein the components are water mixed with aqueous solutions of water soluble polymer and glycolic acid). Accordingly, no new matter has been added.

Applicants reserve the right to pursue the subject matter of any claim as previously presented in related applications, including continuing applications.

### **II. The rejections under 35 U.S.C. § 103(a) should be withdrawn.**

The Examiner rejected claims 6, 7, 10, and 11 as allegedly unpatentable over De Rosa et al. (U.S. Patent No. 6,410,036) in view of Tung et al. (American Journal of Clinical Dermatology, 1(2), pp. 81-88 (2000)). The Examiner also rejected claims 1, 5, 8, 9, and 12 as allegedly unpatentable over Groh (U.S. Patent No. 5,863,943) in view of Tung et al. (American Journal of Clinical Dermatology, 1(2), pp. 81-88 (2000)). The Applicant requests reconsideration of the rejection in view of the amendments presented herein and the following remarks.

#### **A. Rejections based on a combination of references.**

The applicants note that a proper analysis for obviousness requires that "[T]he scope and content of the prior art are ... determined; differences between the prior art and the claims at issue are ... ascertained; and the level of ordinary skill in the pertinent art resolved." *Graham v. John Deere*, 383 U. S. 1. Thus the analysis must include a discussion of the prior art on which the examiner relies. Just as the examiner has addressed the references individually in setting out the rejection, the applicants offer in rebuttal a discussion of what the individual references disclose. This rebuttal discussion cannot be construed as an attack on the references individually; it is simply a discussion of what the individual references disclose so as to ascertain whether the combined teachings support the examiner's assertion of obviousness.

**B. The combined teachings of De Rosa and Tung fail to disclose or suggest a composition comprising an aqueous solution of glycolic acid and polyvinyl alcohol and having the specific pH range recited in independent claim 6.**

A composition comprising an aqueous solution of polyvinyl alcohol and glycolic acid, having a pH of 2.0 or less, is neither disclosed nor suggested by the prior art.

The Examiner relies on De Rosa as teaching an external composition comprising glycolic acid and polyvinyl alcohol and a method of chemically peeling the skin comprising contacting the skin with said composition. De Rosa, however, fails to disclose or suggest that such composition is *aqueous*, which is an element of amended claim 6. In fact, De Rosa *teaches away* from an *aqueous* composition. For example, the abstract of De Rosa indicates that the composition is an anhydrous eutectic mixture. De Rosa describes the mixtures as “non-aqueous, so that the acidic character of the acid component, which is only realized in an aqueous environment, is not present in the mixture.” (De Rosa, column 1, line 67 – column 2, line 3).

The Examiner alleges that Tung teaches that glycolic acid peel products having pH values from 0.1-1.4 are useful in chemical peel procedures, and argues that it would have been obvious to prepare the composition of De Rosa at a pH of 1.4 or less to practice the method of De Rosa, since this pH was known to be appropriate for chemical peel procedures.

The Applicant respectfully disagrees. First, as stated above, De Rosa teaches an anhydrous, non-aqueous mixture -- not an aqueous solution as recited in amended claim 6. Second, De Rosa specifically teaches “a non-irritating base for delivery of potentially irritating acids.” (De Rosa, column 1, lines 66-67). The acidic character of the acid component is not present in the mixture so that it does not irritate the skin. (De Rosa, column 2, lines 1-3) (emphasis added). De Rosa’s compositions do not have a measurable pH. (See, e.g., column 4, lines 19-20.) When the mixture is exposed to the moisture of the skin, only then it is slowly converted to the acid form and released to the skin to provide the benefits achieved by such acids. (De Rosa, column 2, lines 3-8). It would, therefore, defeat the purpose of the teachings of De Rosa to prepare the mixture of De Rosa at the pH of Tung (0.1-1.4).

Stated differently, it would not have been obvious to try to combine Tung and De Rosa because it would not have been obvious to modify De Rosa in a manner that defeats a central purpose of De Rosa. Even if one were to attempt to combine the teachings, one would still want to follow the central tenet of De Rosa that the composition should be an anhydrous one. Because De Rosa teaches away from the claimed invention, an aqueous solution of glycolic acid and polyvinyl alcohol at a pH of 2.0 or less, it would have been unobvious to combine the teachings of De Rosa and Tung to arrive at the claimed invention.

For all of these reasons, the rejection of claim 6 and those claims dependent thereon under 35 U.S.C. § 103(a) should be withdrawn.

**C. The combined teachings of Groh and Tung fail to disclose or suggest a composition comprising an aqueous solution of glycolic acid and PEG as recited in independent claim 1.**

The Examiner alleges that Groh teaches a composition comprising glycolic acid and polyethylene glycol (PEG) “useful in the topical treatment of skin disorders ....” The Examiner acknowledges that Groh does not teach at least the pH limitation of claim 1. In fact, Groh actually *teaches away* from the pH required in claim 1. For example, Groh discloses an emulsion comprising an alpha hydroxyl acid, a non-aqueous moisturizing agent,<sup>1</sup> PEG, a cationic surfactant<sup>2</sup> and water useful as a skin conditioning treatment. Groh states that the composition is “gentle, notwithstanding the use of cationic surfactants, and of acidic pH (approximately 4.0 to 6.0) ... consistent with the natural skin pH.” (Groh, column 7, lines 15-22). Therefore, the composition disclosed in Groh is very different from the composition of claim 1, which requires glycolic acid, PEG and a pH of 2.0 or less.

The Examiner relies on Tung as teaching that glycolic acid peel products having pH values from 0.1-1.4 are useful in chemical peel procedures for the treatment of acne. The Examiner alleges that “it would have been obvious ... to prepare the composition of Groh at a pH of 1.4 or less and to practice method of chemically peeling the skin ... since this pH was known to be appropriate for chemical peel procedures in the treatment of acne ....”

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<sup>1</sup> The claims of the present invention do not require a moisturizing agent.

<sup>2</sup> The claims of the present invention do not require a cationic surfactant.

Applicants disagree with the Examiner's characterization of the art and the conclusion that would have been drawn by a person of ordinary skill, assuming (for the sake of argument) that these references were combined. The Examiner admits in the action that Groh "does not teach ... a method of chemically peeling skin ...." (Action at p. 3.) Rather, Groh explicitly teaches a gentle composition at the natural pH of skin for skin conditioning, including skin moisturizing and softening. (Groh, column 7, lines 15-22). Although Tung does mention a pH of 1.4 for chemical peels on page 87, that is not the purpose of Groh, and is not even the purpose that the Examiner alleges would have been in the mind of a person of ordinary skill for combining the references. Notably, Tung teaches that a pH of 3.8 is efficacious for acne. (See page 86, right column, last paragraph: "...partially neutralized to a pH of 3.8 are efficacious and have a low irritation rate in these groups of patients ...") Tung's pH of 3.8 for acne is within 0.2 pH units of Groh's range of pH 4.0 to 6.0.

Thus, a fairer characterization of the art as a whole is that it would not have been obvious to look to Tung for a way to modify or improve any composition found in Groh, due to their differing purposes. It would have been unobvious to try to combine teachings relating to a gentle skin conditioning composition at natural skin pH with teachings relating to a low pH composition for chemically peeling skin.

However, for the sake of argument, if the references were combined, for the Examiner's purpose of trying to formulate a new composition to treat acne, a person of ordinary skill would have chosen a pH in the range of normal skin, 4.0 to 6.0, as preferred by Groh, or no lower than 3.8, as preferred by Tung to treat acne patients. If one were to combine the teachings of Groh with the teachings of Tung for the purpose of an improved composition, it would have been unobvious to deviate more than about 0.2 pH units from Groh's preferred pH (down to about 3.8, which Tung considered efficacious).<sup>3</sup>

Because none of the cited art specifically discloses or suggests a composition comprising glycolic acid and polyvinyl alcohol at a pH of 2.0 or less, there can be no reasonable expectation of successfully arriving at the claimed invention. In fact, as noted above, the cited art contains teachings that would discourage a person of ordinary skill from attempting to combine the references at all, or from selecting pH values within the claims, even if the Examiner's combination of references were made.

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<sup>3</sup> Because pH is a logarithmic expression of hydrogen ion concentration, the difference between pH of 2.0 and 4.0 represents a 100-fold difference in hydrogen ion.

The composition of the present invention would have been unobvious for additional reasons as well, because acidity is not the only manner by which Groh differs from amended claim 1. Notably, Groh discloses an *emulsion* comprising non aqueous moisturizing components: “The **essential elements that constitute the delivery system** for the AHA are water **and an oil phase to form the basic emulsion** ....” (See and column 2, lines 24-26 (emphasis added); see also the abstract and claim 1 of Groh.) In contrast, the composition of amended claim 1 is an aqueous solution. An aqueous solution does not comprise non-aqueous components in substantial amounts. Thus, the inventions of Groh and of claim 1 are clearly different. The teachings in the Tung document do not disclose or suggest modifying the Groh composition to, e.g., remove oleaginous components and change the character of the composition from an emulsion to an aqueous solution.

When oil drops are applied to the skin, oil drops will absorb into the skin smoothly. In contrast, water droplets do not absorb readily into the skin. Rather, when water drops are applied to the skin, the water drops largely remain as drops on the skin surface. The compositions of the present invention solve such problem of aqueous solutions forming drops on the skin that cannot be applied to and absorbed by the skin uniformly. An aqueous composition comprising the components recited in claim 1 would not have been obvious from the cited art.

One of ordinary skill in the art would have understood that an emulsion, by definition, allows for uniform application and uniform absorption into skin. See, for example “Fragrance and Cosmetic Science – Theory and Practice” September, 1990, pages 352-353 (translation of relevant excerpt from this text text attached). Because aqueous solutions are not known in the art as readily uniformly applied or smoothly absorbed into the skin like emulsions, the present invention provides a novel and unobvious solution to this problem (specification page 1, paragraph 3 and Example 4). Claim 1 recites high-polymerization-degree polyethylene glycol for improving uniform applicability and uniform absorption of an aqueous solution into skin. Groh does not disclose or suggest an aqueous solution nor does Groh mention the problem to be solved in the present invention: the difficulty in uniform application and absorption of an aqueous solution. Therefore, an aqueous solution would not have been obvious from Groh.

For all of these reasons, the rejection of claim 1 and those claims dependent thereon under 35 U.S.C. § 103(a) should be withdrawn.

### **III. Conclusion**

No fees are believed to be due with the filing of this paper. However, the Director is authorized to charge any additional fees deemed necessary to Deposit Account No. 13-2855, under order number 19036/40139. If the Examiner believes that a telephone conversation would expedite allowance of the claims, he is invited to contact the undersigned at the number below.

Dated: July 21, 2009

Respectfully submitted,

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Partial translation of "Fragrance and Cosmetic Science -Theory and Practice" published  
September 1990

p.352-353

### 1.3 Creams·milky lotions

Creams and milky lotions are emulsions (a part is removed). Creams are illiquid, and milky lotions are liquid.

The fundamental composition ingredients of cream or a milky lotion are oily materials, water materials, an emulsifier, fragrance, and other additive agents. Although an O/W type emulsion and a W/O type emulsion are made according to the ratio of oily materials(oily phase) and water materials(water phase), and the kind of emulsifier, since a milky lotion has little oily phase compared with cream, it is almost an O/W type emulsion. (Physical chemistry of cosmetics: The clause of emulsification, reference).

Since creams and lotions have taken the form of the emulsion, generally it has the following features.

- (1) Since creams and milky lotions mix with oily materials and water materials, it has a different feeling of use and the appearance from the case where oil and fat are used independently.
- (2) A qualitative effect (effect) improves further by incorporating oil-soluble material, and water-soluble materials during the same prescription.
- (3) By making it an emulsion, the action given to the skin can be easily adjusted and changed by the kind of oily phase or phase ratio.
- (4) By adjusting the degree of consistency of an emulsion, the product which suited the various purposes of use can be made.
- (5) An emulsion gives an effective ingredient uniformly on the skin to the skin, and promotes an effect by osmosis on the skin.
- (6) The protective action of the skin, skin softening, and skin moisturising are given by both oily ingredient and moisturising ingredient.

Various products are made when these features change the kind of oily phase, phase ratio, and an additive agent, etc. by the kind of cream and milky lotions, the purpose of use, etc.

(END)



# 香料品科学

理論と実際

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カオリン	1.0
セリサイト	1.0
グリセリン	4.0
エタノール	14.0
フェノール	0.05
d-カンフル	0.15
防腐・殺菌剤	適量
精製水を加えて	100.0

カラミンは本来酸化鉄を含む天然の炭酸亜鉛を焼成してつくられるものにつけた名称であるが、現在は酸化第二鉄 ( $\text{Fe}_2\text{O}_3$  : ベンガラ) を酸化亜鉛に加え焼成してつくられる。

緩和な収れん作用があり、皮膚の保護と乾燥作用を有する。医薬用としてはカラミンが8%程度含有されており、紅斑、丘疹などをともなう皮膚炎や湿疹に用いられている。

フェノールは止痒および鎮痛効果があり、カンフルは皮膚に冷感を与え、日焼け後の皮膚の熱感（ホテリ）をしずめる目的で配合される。

以上化粧水を一般的分類により説明したが、市販品の中にはハンドローションやボディローション、スキンローションなど、使用部位を冠した名称の化粧水も市販されているが、これらは前述のいずれかに属すると考えてよい。

なお化粧水の一般的な製造法については、第8章を参考にされたい。

### 1・3 クリーム・乳液類 creams・milk lotions

クリーム・乳液類は、一部のものを除いて乳濁系 emulsion で、流動性のないものを一般にクリームといい、流動性のあるものを乳液と呼んでいる。

クリームや乳液の基本的な構成成分は、大別して油性原料、水性原料、乳化剤、香料その他の添加剤よりなっている。油性原料（油相）と水性原料（水相）の相比率および乳化剤の種類によりO/W型エマルジョンとW/O型エマルジョンができるが、乳液はクリームに比べ油相量が少ないので、ほとんどO/W型エマルジョンである（化粧品の物理化学；乳化の項参照）。

クリー  
ような特  
(1) 油  
で月  
(2) 油  
一層  
(3) エ  
える  
(4) エ  
た塵  
(5) 皮  
果を  
(6) 油  
与え  
これら  
や相比率  
1・3・  
(1)  
化粧用  
および法  
(2)  
1) 併

クリーム・乳液類は、エマルジョンの形をとっているの、一般的につぎのような特徴を有する<sup>19)</sup>。

- (1) 油性原料と水性原料とを混和（乳化）したものであるから油脂類を単独で用いた場合と異なった使用感および外観がある
- (2) 油性性の原料と水溶性の原料とを同一処方中に組み入れることにより、一層質的效果（効能）の向上をはかることができる
- (3) エマルジョンにすることにより、油相の種類や相比率により、皮膚に与える作用を容易に調節、変換することができる
- (4) エマルジョンの粘稠度を調整することにより、種々の使用目的に適合した製品をつくることができる
- (5) 皮膚に対して有効な成分を皮膚上に均一に与え、皮膚への浸透により効果を促進する
- (6) 油性成分と保湿成分との両者により皮膚の保護作用、柔軟・湿潤作用を与える

これらの特徴は、クリーム、乳液類の種類、使用目的などにより油相の種類や相比率、添加剤などを変えることによって種々の製品がつけられる。

#### 1・3・1 クリーム

##### (1) クリームの分類

化粧用クリームは、その使用目的（機能）や油相の量により一般に表6.9および表6.10のように分類される。

##### (2) クリームの皮膚への作用

###### 1) 保護作用

表6.9 使用目的（機能）からみたクリームの分類

目的(機能)	製品一般名称
皮膚の清浄・化粧おとし	クレンジングクリーム
皮膚の血液循環促進	マッサージクリーム
皮膚の保護、保湿、柔軟	エモリエントクリーム、ナリシゲクリーム、ナイトクリームなど
化粧下地	ベースクリーム



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## 化粧品科学—理論と実際

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